

REMARKS/ARGUMENTS

The Examiner is thanked for indicating that claims 78, 81, 84, 87, 90, 93 and 96 set forth allowable subject matter.

Applicant respectfully requests that the Examiner reconsider allowance of the base claims from which these claims depend for the reasons set forth below in connection with the rejection under 35 U.S.C. §112.

Claims 2, 39, 42, 45, 48, 51, 54, 57, 60, 63, 66, 69, 72, 75, 99 and 102 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly overbroad. The Examiner correctly points out that these claims recite selective estrogen receptor modulators ("SERMs") not limited to the benzopyran structures which are applicant's preferred embodiment. Nonetheless, it is believed that applicant's showing of an advantage in combining sex steroid precursors with benzopyran-type SERMs would lead one of skill in the art to expect success in making that combination with other SERMs. Enablement does not require absolute certainty of success for every single specie within a claimed genus. Instead, it requires only a reasonable expectation of success. The interchangeability of various SERMs for various purposes is believed to provide this likelihood of success for the following reasons.

In the present claims, there is a recitation of a class of like-functioning materials (e.g., "selective estrogen receptor modulators"). Such recitations of a class of materials is proper under 35 U.S.C. §112, first paragraph, wherever the specification would lead one of skill in the art to expect and predict that specific members of the class will interchangeably provide the same function in the invention. In Re Hirschler, 591 F.2d 693, 701, 200 U.S.P.Q. 711 (C.C.P.A. 1979). Even if the materials may perform different functions, in other contexts, they may nevertheless be claimed as a class where they perform the same function in the invention. id. For example, the application at issue in Hirschler gave only a single example of a single steroid (dexamethasone 21-phosphate), in a claim that broadly recited all "steroids" as a class of materials whose penetration of human skin could be enhanced with DMSO. The Court of Customs and Patent Appeals permitted broad claim language to "steroids" generically. The Court pointed out that although different steroids have vastly different functions biologically

(consider, for example, male steroids such as testosterone versus female steroids such as estradiol), the entire class of steroids would act identically in the context of the claimed invention (i.e. in enjoying DMSO-enhanced skin penetration). The Court noted:

The question is simple: does the array of information supplied by appellant in the [relevant] application teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process. We conclude that it does.

* * *

Steroids, when considered as drugs, have a broad scope of physiological activity. On the other hand, steroids when considered as a class of compounds carried through a layer of skin by DMSO, appear on this record to be chemically quite similar.

Hirschler, 591 F.2d at 701, 200 U.S.P.Q. at 717 (emphasis added).

Where the members of the generically recited class are expected to perform similarly in the invention, the dictates of §112 are met. There is no magic number of specific examples required. A single example was sufficient in Hirschler. Indeed, a specification without any examples can be sufficient in the appropriate case. See, e.g., In re Strahilevitz, 668 F.2d 1229, 1232, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982); In re Stephens, 529 F.2d 1343, 1345, 188 U.S.P.Q. 659, 661 (C.C.P.A. 1976); In re Borkowski, 422 F.2d 904, 908, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970); In re Gay, 309 F.2d 769, 774, 135 U.S.P.Q. 311, 316 (C.C.P.A. 1962). All that is required is a rational basis for expecting that the advantages of the invention will not be lost simply because one member of a generically recited class is chosen instead of another. For all of the foregoing reasons, it is urged that the Examiner's rejection under 35 U.S.C. §112 should be withdrawn.

Finally, in applicant's prior Amendment mailed May 5, 2003, applicant noted that Labrie '201 (one of applicant's own publications cited by the Examiner) did not identify the benzopyran compounds disclosed as selective estrogen receptor modulators. It was noted that this was not discovered until later. Applicant wishes to clarify that this refers to applicant's later discovery of the SERM nature of these compounds, i.e., later than the filing date of Labrie '201. The prior art has discussed benzopyran compounds regarding their physiological effect on parameters such as

bone and cholesterol (see enclosed Information Disclosure Statement). Applicant's basic point is that the prior art is not believed to have disclosed or suggested the advantage of combining selective estrogen receptor modulators with sex steroid precursors for lowering cholesterol as taught herein.

It is believed that the application is now in condition for allowance. Issuance of a Notice of Allowance is solicited.

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January 16, 2004

Name of applicant, assignee or
Registered Representative

Signature

January 16, 2004

Date of Signature

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